UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO: 1629

Master File No. 04-10981

THIS DOCUMENT RELATES TO:

ALL PRODUCTS LIABILITY ACTIONS

VIDEOTAPED DEPOSITION OF: CHERYL D. BLUME, Ph.D.

DATE: November 12, 2007

TIME: 9:25 a.m. to 6:07 p.m.

PLACE: 13902 North Dale Mabry Highway
Suite 122
Tampa, Florida

PURSUANT TO: Notice by counsel for Defendants for purposes of discovery, use at trial or such other purposes as are permitted under the Federal Rules of Civil Procedure

BEFORE: VALERIE A. HANCE, RPR
Notary Public, State of Florida at Large

Volume 1
Pages 1 to 370

Mr. -- prepared by Mr. Altman in connection with that NDA?

A. The only thing that is publicly available from a new drug application is the information that the FDA provides relating to that new drug application. And I don't know if the FDA's release of the clinical data section includes an overview of the postmarketing pharmacovigilance. I don't know.

Q. And what's the name of that drug?

A. I just can't share this with you.

Q. Well, just so I understand, you did work on behalf of a pharmaceutical company in regard to a new drug application, correct?

A. Yes.

Q. And that your -- your client submitted that information to the Food and Drug Administration in connection with seeking FDA approval for a drug?

A. Yes.

Q. And now is it your testimony that the drug was subsequently approved by the Food and Drug Administration?

A. Yes.

Q. And you're claiming that the work that you submitted to the United States Government is somehow confidential in connection with that approval of -- of a

drug for marketing to the United States?

A. Yes.

Q. I'm asking you -- so you're just refusing to provide me with the name of the drug?

A. All the work that I provide goes to the client and is embedded within their new drug application.

Q. What's confidential with the name of the drug?

MR. FROMSON: Just note my objection as to form.

THE WITNESS: I am not permitted to talk about the clients nor their drug products.

BY MR. BARNES:

Q. By whom?

A. By the client.

Q. Are you relying on any of your experience working with these pharmaceutical clients in forming your opinions in this case?

MR. FROMSON: Note my objection as to form.

THE WITNESS: My opinions in this case are -- are predicated upon my 25 years in the pharmaceutical industry as well as the work that I have continued over the last six years.

BY MR. BARNES:

Q. Are you relying on any of the work you've done with the Food and Drug Administration in connection with

pharmaceutical clients in expressing any of your opinions in this case, including the methods that Mr. Altman employed on your behalf in making these submissions?

A. No. Not specifically, no.

Q. Not specifically. How about generally?

A. He does the same general types of searches in both litigation and as well as in the product development assignments.

Q. It's not my question.

MR. BARNES: Would you read back that last question, please.

(The reporter read the portion requested.)

THE WITNESS: It is the same methods that he uses for both our litigation work as well as pharmaceutical development work. So I'm relying on the experience I have gained with him in the litigation for my work in this case.

BY MR. BARNES:

Q. Please list every drug pharmaceutical client that Mr. Altman has assisted you with --

(Brief interruption.)

MR. FROMSON: Did you finish the question?

MR. BARNES: I did not. Thank you.

MR. FROMSON: Okay.

BY MR. BARNES:

Q. Please list for me each pharmaceutical client with whom you have provided services and have engaged the services of Mr. Altman of Finkelstein & Associates --

MR. FROMSON: Object --

BY MR. BARNES:

Q. -- for me.

MR. FROMSON: Okay. Now, just note my objection again to the extent that she's already indicated that confidentiality agreements from those pharmaceutical companies --

MR. BARNES: Make your record.

MR. FROMSON: I thank you.

-- prevent her from answering that question.

THE WITNESS: Yes, I can't answer it.

BY MR. BARNES:

Q. Would you please -- you're refusing to answer the question?

A. Well, I'm refusing because I am not permitted to answer the question.

Q. Would you please provide me with confidentiality agreements with these companies with the names redacted?

MR. FROMSON: Just note my -- my same

THE WITNESS: I don't know if I can answer that question. I can answer that he was identified in the courtroom one time at a Phen-Fen trial. So I can identify that one. But other than that, I don't know if I'm permitted to answer that.
BY MR. BARNES:
Q. Let's do it this way. You've -- you've identified Mr. Altman as someone with whom you have worked on pharmaceutical litigation in the past?
A. Yes.
Q. Okay. And he's obviously -- do you know, if in doing so, was he engaged with Finkelstein & Associates or is it something that he was freelancing on --
MR. FROMSON: Just note --
BY MR. BARNES:
Q. -- when he did these -- when he did his work with you?
MR. FROMSON: Just note my objection as to form in terms of time, as well as whether it was one or the other or both.
MR. BARNES: Well, let's -- let's -- let's just break it down.
MR. FROMSON: Okay.
BY MR. BARNES:

Q. And you've worked with Mr. -- Mr. Finkelstein's firm in the past, correct?
A. Yes.
Q. On how many cases, different litigations, have you been engaged by the Finkelstein law firm in pharmaceutical litigation?
A. Have I been engaged by the Finkelstein law firm?
Q. For -- yes, we'll do engaged first.
A. One other.
Q. What --
A. One other case besides this.
Q. What's that?
A. I have no idea if I'm permitted to answer that.
Q. Are you -- are you refusing to answer the prior cases you've handled with the Finkelstein law firm?
A. I also have an agreement and confidentiality agreement with them --
Q. Will you produce that confidentiality agreement?
A. -- in our contract, yes.
If they permit me to do that, I will ask them at the break.

Q. So you are -- you are refusing to identify the litigations that you are involved with with the Finkelstein law firm in this deposition; is that correct?
MR. FROMSON: Just note my objection as to form, to the extent that you're not only harassing her. She said she would consult with counsel.
MR. BARNES: Well, we have -- we have -- we -- we have a limited period of time. It's been not the most convenient spot to do a deposition. We're trying to accommodate you. Are you instructing her not to identify the cases which she's --
MR. FROMSON: Did I make an objection?
MR. BARNES: No, you -- I just --
MR. FROMSON: I did not make an objection.
BY MR. BARNES:
Q. So are you refusing to answer that question?
A. I simply don't know if I'm permitted to answer that question. If I am permitted, I will answer it.
Q. Who would you have to speak with to find out if you're permitted to answer the question about the Finkelstein associate relationship?
A. Well, I would -- I would think that I could ask Mr. Fromson that question.
Q. I would -- I would -- is Mr. Fromson in this

room?
A. Yes.
Q. And is he seated right to your left?
A. Yes.
MR. BARNES: Okay. Mr. Fromson, are you -- would you permit her to identify the litigations with your law firm that she is currently working on or has worked on in the past?
MR. FROMSON: I think it's entirely appropriate that at a break I simply speak with the witness to identify the case that she believes she's referencing, and then I can confer with you after.
BY MR. BARNES:
Q. Do you recall providing a list of litigation cases you've testified in in the past?
A. Yes.
Q. Okay. Let's go through it that way.
Name the pharmaceutical products with whom you have -- you provided consulting services in the past ten years.
MR. FROMSON: Just note my objection to form.
Can you -- I just want to have that question read back for one second.
So you want to know about consulting services

Q. You may answer.
THE WITNESS: Do I answer?
BY MR. BARNES:
Q. Yes.
A. Mr. Altman is hired to do this because he has a specialty in filtering, or whatever more sophisticated term that should be applied to it, these databases. He is used for this in our -- in our work and in other people's work.
He was asked by the FDA years ago to validate his efforts, and FDA confirmed his method. I would not be able to completely validate what he does. But once the FDA statisticians and epidemiologists approved NDA's using his method, I have accepted his method.
Q. How do you know that --
A. And --
Q. I'm sorry.
A. And as you will know through my discussions of the data, my opinions are certainly not predicated upon these individual databases any more than they are on other events in this database. So while the information is important and while it agrees with other opinions, it is not the ultimate opinion, but I accept his work based on persons far more knowledgeable and skilled in this area than I.

Q. Did FDA review his work in this case?
A. No.
Q. In the Neurontin case?
A. No.
MR. FROMSON: Just note my objection as to form.
THE WITNESS: He -- they -- they reviewed and validated his approach of the FDA databases and other databases.
BY MR. BARNES:
Q. Which you won't produce to me yet at this point for me to examine you on?
A. Well, I'm certainly willing to ask if I may do that, but you would certainly not ask me to violate my confidentiality or contracts.
Q. Not today. I'm not going to ask you to do that today. I've asked -- we'll take it up with the court if we have to.
But have you --
A. No, I have not validated his work.
Q. Okay. And so you don't know the rate of error in his work in the report, do you?
MR. FROMSON: Objection as to form.
THE WITNESS: If -- if there is any errors. I don't know if there is any errors.

BY MR. BARNES:
Q. One way --
A. The error -- the error rate was acceptable when he did a far more difficult assignment.
He -- the -- the NDA work that he does for us is far more difficult than this work. And the rate of errors were -- if any, were certainly acceptable.
Q. That's not my question.
A. I know, but I'm trying to answer your question.
Q. I understand you are, but listen to my question, okay, and we'll just keep moving on.
My question is in connection with the work he has done on pages -- in your report -- 60 -- you've identified Pages 69, 70, 71, 72, 73, 74, 75. We don't know about 76.
For example, you have not gone back and -- and established the error -- any -- the rate of error in the filtering he did for you prior to this deposition, correct?
MR. FROMSON: Objection to the extent that it hasn't already been asked and answered.
THE WITNESS: Correct, I have not done that. He may well have underestimated the reports. No, I'm kidding. He -- I have not checked anything.

I'm not capable of validating his work.
BY MR. BARNES:
Q. So it is your testimony that you have never specifically done anything to validate his data in 2007 on his work in Neurontin?
MR. FROMSON: Same objection, to the extent that it hasn't already been asked and answered.
THE WITNESS: Yes, I have not -- I am not capable of independently validating his extraction of data from -- from these databases.
BY MR. BARNES:
Q. At any time in this litigation, correct?
MR. FROMSON: Same objection to the extent that it has not already been asked and answered.
THE WITNESS: Yes.
BY MR. BARNES:
Q. Okay. Now, let's -- let's finish going through your report and identify other tables that Mr. Altman --
A. Okay.
Q. -- filtered for you.
A. Okay. And, again, I don't -- I don't mean to -- to limit what he does as filtering. That's simply my shorthand way of referring to it.
The Pfizer database --

Q. Is -- are -- is -- is -- are the analyses that Mr. Altman prepared for you, as you've defined it in this litigation, important to your opinion in this case?

MR. FROMSON: Just note my objection as to the form. That's an ambiguous question.

THE WITNESS: Well, I think that everything I have in here is important. I mean, the World Health Organization database is important to me. Yes, they're all important to me.

BY MR. BARNES:

Q. So if -- if Mr. -- is it your testimony that if you extracted the SRS database analysis and the analysis based on the internal Pfizer databases that your opinion would be the same with regard to the signal analysis?

A. Well, the Pfizer database was also repeated in the 2004 NDA records. So, I mean, even if I lost the Pfizer databases, I would still have their analyses of those databases in the NDA submission.

Yeah, my opinion would still be the same, because there -- there was an amazing similarity in signals and conclusions across SRS and WHO and even the Health Canada database.

Q. Just so I understand though, you -- so your -- the absence -- you do not need the SRS database analysis

to form your opinions with regard to signals?

A. Well, it's almost an impossible question to answer. We are required to assess the SRS database for signals. I mean, FDA has criteria on how one data mines the database. So, yes, it's important to me, but we additionally mined the WHO database and we looked at the mining efforts of your client in their internal database and in the materials they redid in 2004. So my opinion is not dependent on any one issue.

And if, as you read the conclusions, I go across -- I conduct pharmacovigilance across databases, not dependent on one database. Now, if one database were remarkably different than the other one, we might go back and check that again.

Q. Okay. Let's move on. One --

A. What page are you on?

Q. 120, I think, is my next table. Who prepared that?

A. This is the internal database, and I believe this was Mr. Altman on through 120 -- let's see -- 127.

Q. So from 120 to 127 are various tables of reports of adverse events that Mr. Altman extracted from the Pfizer internal database between 1996 and 2002, correct?

A. Yes.

Q. And, again, did you audit or in any way validate the work product you received from Mr. Altman on pages 120 to 127?

A. No.

Q. Okay. What's on 128? This is PSURs, annual reports? Or is this the internal Pfizer adverse event database?

A. No, this is not -- this isn't PSUR. These are -- this is the internal database.

Q. So then, again, this is Mr. Altman's work, correct, on 128?

A. Yes. And these are for -- well, in part.

Your client did a partial amplification of their label in '96 to include some additional postmarketing events. And the ones listed on the page are the ones that Pfizer chose to put into the package insert at that timeframe.

Q. You say the word "Pfizer" in 1997. Is it your testimony that Pfizer, Inc., modified the label in 1997?

A. Well, I think they -- I'm using "Pfizer" to refer to them all. I think Pfizer came in around 2000, but when I say "Pfizer," I'm referring to Parke-Davis and Warner-Lambert.

Q. Is it important to you to be accurate in the way you -- you testify in terms of what corporation,

what party conducted certain analyses?

A. I think in the report I talk about the different -- who submitted the different reports, when they were submitted, at different time points. But for the purposes of discussion, I have been just using the term "Pfizer."

Q. Well, for purposes of this deposition, when I use the term "Pfizer" and I use the term "Parke-Davis/Warner-Lambert," they're two different corporations. Do you understand that?

A. I do, but I also looked in the database and couldn't find anywhere when Pfizer did -- did assume control that they corrected anything that Parke-Davis did.

Q. That's not -- that's not the question.

A. So since that time, I have just referred to everything as "Pfizer."

Q. Well, what -- so is it your view that you just lump everybody together no matter who's actually involved as a matter of fact?

MR. FROMSON: Just note my objection as to form.

THE WITNESS: I don't -- I don't understand.

BY MR. BARNES:

Q. Well, when you say the word -- when you say

"Pfizer," Pfizer -- you understand that to be Pfizer, Inc., a corporation, right?
A. I guess, yes.
Q. And if Pfizer -- so -- so you're willing to say "Pfizer," just lump the defendants together under the rubric Pfizer even if it's inaccurate or misleading or unfair?
MR. FROMSON: Just note my objection as to form.
THE WITNESS: That's just simply the way it's been referred. I've just referred it as to the last one. If you want, I can go back and at various time points specifically note which one it is, but my understanding of the -- of the concern has gone from the beginning until now.
BY MR. BARNES:
Q. Well, where you understand it's Pfizer, Inc., that has prepared the table or have -- has provided analysis or not used the -- I'd appreciate if you'd use the word "Pfizer, Inc.," so I can ask you questions that way. And if it's a prior -- if it's Parke-Davis or Warner-Lambert that is responsible for the preparation of the event, to the extent you -- you can say that, I would appreciate it. It would make our -- it would make the deposition go quicker, because I'm going to ask you

these questions: "What is the basis on Pfizer, Inc., dated?"
"Oh, I just lumped them all together."
So to the extent you're capable of actually differentiating between corporations and parties in this litigation as to who did what, that would be appreciated.
MR. FROMSON: Just note my objection as to the form of the last question.
THE WITNESS: Right. Well, I can make it even easier than that. I have all of the annual reports and the PSURs and IND annual reports in the room, so when you ask the question, I will get up and actually get the annual report --
BY MR. BARNES:
Q. Well --
A. -- so I answer it specifically.
Q. When -- when did Pfizer -- do you understand when Pfizer, Inc., acquired an interest and Warner-Lambert acquired the company?
MR. FROMSON: Just note my objection as to the form of the question, in terms of it having a legal conclusion when you use the term "acquire interest."
THE WITNESS: I think it's 2000.

BY MR. BARNES:
Q. Okay. So -- okay.
In 1996, who had the -- the approval by the Food and Drug Administration to market Neurontin in the United States?
A. Oh, I don't -- I don't know if one was marketing. I don't know the difference between the Parke-Davis and Warner-Lambert issue. I don't know.
Q. Just say Warner-Lambert, who --
A. Okay. Warner-Lambert. I don't know. I have no idea. But I have the report, so if you want a --
Q. No, I -- do you --
A. If you want a correct answer, I will get up and get the reports.
Q. Why don't we do this.
You don't know who filed the data in fourth quarter of 1996, do you? You don't know what company filed it, do you?
A. I -- I think it's Parke-Davis, but I'm not sure. But I have the reports, so why don't I get up --
Q. You know it's not Pfizer, correct?
A. Well, I think -- I think Pfizer is 2000. But I have the reports, so I don't know why you're questioning me this way when I can get up and get them.
Q. Just when you say "Pfizer," you should be

intentional as to what you're saying about Pfizer. And if another company filed it, then I'd appreciate if you'd -- you direct your --
A. Well --
Q. -- your -- your -- your answers to that.
A. I will --
Q. We'll proceed. I'll correct you every time if I have to. Okay?
A. Okay.
Q. So this is an Altman analysis on 1996, 1997, correct?
A. Page?
Q. Page 128.
MR. FROMSON: Hold on. Just note my objection to the form of the question as "Altman analysis."
THE WITNESS: Yes.
BY MR. BARNES:
Q. Okay. And did you -- again, you didn't validate this work, did you?
A. No.
Q. Is it fair to say -- just so we don't have to ask this every time you identify Mr. Altman as the source of the -- of the tables, is it fair to say that -- that you've not independently validated or tested any of the tables that Mr. Altman provided to

you, correct?
A. That is correct.
Q. Okay. When's the next one? What's the next table? I have one on 130. And this is the World Health Organization.
A. Yes, I see on it -- just getting back to your previous criticism, I see on the front page that I have specifically noted that "Pfizer defendants" will refer to Warner-Lambert, Parke-Davis, and Pfizer. And I think the tables do -- are coded as "Pfizer defendants."
So if it makes it easier, I will say "Pfizer defendants" instead of "Pfizer."
Q. Well, now -- but I -- but I think -- do -- do you think it's misleading to have -- to say the word "Pfizer defendants" to -- which includes Pfizer in -- in a report or a regulatory activity or a marketing practice that predated their -- their ownership of the company? That's -- that's --
MR. FROMSON: Just note my objection as to form.
THE WITNESS: I think that I referred to all three clients and I -- no, I don't think it makes a bit of difference as to what my conclusions are. No.
BY MR. BARNES:

Q. So accuracy as to -- as to which entity actually submitted the report is not important to you as a scientist or regulatory affairs professional?
A. Well, of course -- of course.
MR. FROMSON: Just note my objection as to the form of the question. Misstates her testimony.
THE WITNESS: Yes, of course that's important, but I specifically said here I was accessing and reviewing data from all three. And I was very careful to say "Pfizer defendants."
But I don't see "Pfizer" in here. I say "Pfizer defendants."
BY MR. BARNES:
Q. Well, what if you would -- are definitions important to you as a scientist and regulatory affairs professional?
A. Of course they are.
Q. And if your definition is somehow misleading or biased or inaccurate, wouldn't you think it would be important to correct it on the record here today if you have a chance?
A. If I'm referred --
MR. FROMSON: Note my objection as to form.
THE WITNESS: I'm referring to it as "Pfizer defendants." "Pfizer defendants" include all

three.
BY MR. BARNES:
Q. Okay. All right. Then let's go to page 132. Who prepared that?
A. PDG.
Q. And next one, please. Next table.
A. PDG for pages 132, 133, and 134.
Q. Okay.
A. And 135.
Q. How about 137? These are the Poison Control Center reports.
A. Yes. And there was a journal article that accessed all of this information. And I believe this table derives directly from the AGEM (sic), American Journal of Emergency Medicine Report.
Q. And who prepared this table?
A. PDG.
Q. Okay. How about the DAWN table on page 143?
A. I believe PDG did that.
Q. How about the tables on 145 and 147 -- 6?
A. Okay. The -- this was done by PDG and these refer back -- this is similar to what we have already discussed. These refer back to research reports that were generated during this time period.
Q. How about 165?

A. Okay. We've now moved into the fourth category, June 2002 to present.
Q. This is PSUR, so I assume PDG did it, on 166?
A. 163, I think was skipped. That was PDG.
Q. Uh-huh. (Indicates affirmatively.) Thank you.
A. 165 would be PDG. 166. And then we're back to the AERS database on page 167.
Q. And -- okay. 167, 168 would be work that Mr. Altman provided to you, correct?
A. Correct.
Q. These are SR -- these are AERS database --
A. Yes.
Q. -- tables, correct?
A. Correct.
Q. And then World Health Organization would be PGD?
A. Would be PDG.
Q. PDG.
Okay. And then the next table I have is two -- really, maybe you can explain to me what they are. Going to page 193, 194, and 195.
A. One, these tables relate to a dany (sic) -- a data mining effort recognized by the agency, recommended by the agency, called PRRs or percent comparison across

products as percent reports. Both of these tables were done by Mr. Altman.
Q. Who directed that these tables be prepared?
A. The table in 194 is a table across comparisons of different antiepileptic drugs. It's a standard way that we have tried to pictorially present the data that we looked at earlier in comparison to other sister drugs. I asked that that be done.
Q. And so you directed this analysis?
A. Yeah, this is a routine analysis for us in our work when we're -- when we have drugs that are part of a class.
And I had -- page 195 is a comparison from another trial -- another project that I guess Mr. Altman is working on. But it illustrated the same sort of separation within a class.
Q. So Mr. Altman prepared this chart on page 195, correct?
A. Yeah, well, he did 194 and 195.
Q. Did both of them?
A. Right.
Q. Okay. Did you do any independent work to validate the graph on page 194 or on page 195?
A. No.
Q. And so you don't know if there is a rate of

error for the data depicted on page 194 which is entitled "PRR Over Time, Suicidal and Self-Injurious Behavior HLT," correct?
A. I don't know if there is any rate of error and I --
Q. One way or the other?
A. I don't have a -- no, I did not validate it.
Q. Did you -- did you -- you said something about this is how -- at page 194, 195 -- this is how you routinely do these analyses for other -- other clients?
A. No, for pharmacovigilance work.
What this does is, we're interested in this case in Neurontin, so Neurontin will be on the chart, but as pharmacovigilance assignments, you're always interested if a particular adverse event is simply part of the -- is part of what is observed with that class of drugs or whether there is something unique with --
(Phone ringing.)
THE WITNESS: Somebody is calling in.
-- whether there is something unique with your drug.
So what one does, what we are -- what is suggested, what we are taught to do is to do these PRR ratios. Because if there is something unique

about a drug, it will look different in a PRR time, time-derived data, than will the other drugs in the class.
BY MR. BARNES:
Q. Who chose the drugs on page 194 for comparison?
A. Oh, I -- I don't know if we did these. I -- I think I mentioned in my report Gabitril. I know we talk about carbamazepine. I don't -- I don't know if we did that collectively or if I sent the list one. I don't know.
Q. So it's possible that Mr. Altman chose the comparator drugs --
A. Well --
MR. FROMSON: Just note my objection.
BY MR. BARNES:
Q. -- on this graph?
A. I --
MR. FROMSON: I'm sorry. Just note my objection as to form.
THE WITNESS: I don't recall how we did this. We had to do it in a -- we had to pick drugs that would have data across the relevant time period, so we couldn't use an -- an AED that were approved in 2003 or 2004, because it wouldn't have the data.

So I -- I don't -- whether we collectively did this or not, I just don't recall.
BY MR. BARNES:
Q. So it's possible that Mr. Altman chose the comparator drugs, correct, without your supervision?
MR. FROMSON: Note my objection as to form.
THE WITNESS: I recall the discussion of including Gabitril in there. I know that I remember that. Now, I just don't recall.
BY MR. BARNES:
Q. You say "class of drugs." What do you mean by a class of drugs?
A. Well, when you look at pharmacovigilance data, you're interested, of course, in the -- in the drug in question for that particular NDA, but you're also interested in other drugs that are chemically similar to that drug, whether it's used for the same indication or not, so you do that comparison. You compare the adverse event of interest with other drugs that are approved for the same indication, and you also approve drugs that have the same mechanism of action. So there is different ways that you canvas pharmacovigilance data.
In this particular table or this particular graph, what we have here are the PRRs for the suicide-related events, the high-level term

an answer to that question.
(The reporter read the portion requested.)
MR. FROMSON: I just note my objection as it misstates her testimony.
MR. BARNES: That doesn't relate to her testimony.
BY MR. BARNES:
Q. Can you answer that question, please?
A. There were multiple reasons why we picked the cuts that we did.
Q. What was -- was one of them the notoriety bias from publicity surrounding Neurontin that occurred after 2002?
A. I recall that we specifically discussed that in a -- in a variety of ways. Whether I was specifically thinking about that when we made the cut in 2002, I think I was. But at the end of the day, the 2002 data support that there was an increase in suicide, it has nothing to do with these ads or with Dr. Franklin's findings.
So I have covered the period of time that precedes any of these notoriety biases you are concerned with.
Q. What other reasons other than notoriety bias caused you -- that was one reason, correct? Just make

sure I have that understood, that one of the reasons you chose the end of 2002 was because of the effect of notoriety bias on adverse event reporting, correct?
A. No.
MR. FROMSON: Objection as to form.
THE WITNESS: What I said was, I had to find some ways to cut this huge amount of time. 2002 reflects a postherpetic neuralgia approval and the -- and the ANDA -- or the NDAs include the postherpetic neuralgia.
When we were deciding on the times, I recall the discussion about the advertisements. There was a big influx in the number of events and the Franklin revelation became public. So by cutting it in 2002, we were able to resolve all of those concerns with the 2002 date.
BY MR. BARNES:
Q. So let me -- that's fine. Let me make sure I understand the two points.
One was, in 2002, there was a new indication that was approved for postherpetic neuralgia, correct?
A. Yes.
Q. The other thing that caused you concern was the notoriety bias due to publicity between Neurontin and a -- a guilty plea concerning off-label promotion as

well as attorney advertising, correct?
MR. FROMSON: Objection, form.
THE WITNESS: Well, I'll repeat it again.
I recall that we had a discussion regarding the advertisements, regarding the guilty plea, and how we were going to divide up the database.
BY MR. BARNES:
Q. Were there advertisements regarding the guilty plea?
A. No, regarding advertising in 2003, The ramifications in early -- in 2004 with the guilty plea -- I think it was in May -- and the postherpetic neuralgia was approved in 2002.
There was some comment that postherpetic neuralgia does not have a very big database, so it really wouldn't make that big of a contribution to a database that was already 90 percent driven by off-label uses. But by cutting it at 2002, we will be able to avoid any of these influences or notoriety bias. So, luckily, in 2002, we've avoided this problem.
Q. Okay. And -- and -- and after 2002, did you make any effort to quantify the effect of notoriety bias on adverse event reporting that occurred after January 1, 2003?
MR. FROMSON: Objection to the -- it's been

asked and answered.
THE WITNESS: Yeah, I -- I -- no. I made no attempt either -- for either of the instances that could have impacted notoriety bias.
MR. BARNES: Okay. Let's take a short break. I'm going to clean up from my exhibits and go on to the next area. Thanks.
THE VIDEOGRAPHER: Off the record 2:25.
(Recess taken.)
THE VIDEOGRAPHER: On the record at 2:38 p.m.
BY MR. BARNES:
Q. Dr. Blume, I want to go back to some of your qualifications in this case, if we might. Okay?
Dr. Blume, are you a medical doctor?
A. No.
Q. Are you permitted to prescribe medicines in the United States to patients?
A. No. I have a Ph.D.
Q. Okay. And your Ph.D. is in what?
A. Pharmacology and toxicology.
Q. And in the course of your career as a toxicologist and pharmacologist, have you ever had to read a prescription drug label for the purposes of balancing potential risks and benefits of the medication for an actual patient?

A. Same answer. I'm not a prescriber, so I cannot be an expert in psychiatry.
Q. Are you an expert in suicide?
A. Same answer. Not a pre- -- not a physician, not a prescriber, not a psychiatrist, not a suicidologist.
Q. Are you an expert in pain management?
A. Same, not a prescriber.
Q. Well, will you answer --
A. Not a pain management expert.
Q. Are you an expert in the field of epidemiology?
A. Well, I'm not an epidemiologist, but, of course, as you can tell from all the work we've done today, I use epidemiologic assignments and principles in our work with our pharmaceutical clients.
Q. Are you a qualified epidemiologist?
A. No, I'm not an epidemiologist by training.
Q. Okay. And when you do epidemiological research, you often employ Mr. Altman to assist you in running certain inquiries to FDA databases and other databases, correct?
A. Well --
MR. FROMSON: Objection as to form.
THE WITNESS: -- Mr. Altman does run databases

for us in our epidemiology work; that is correct.
BY MR. BARNES:
Q. Okay. Now, are you an expert in the field of epilepsy?
A. No, not a -- not a physician, not a prescriber, not a neurologist, so I'm not an epileptologist.
Q. Same question as to neuropathic pain.
A. Same answer.
Q. You're not an expert, correct?
A. Not a physician, not a prescriber, not a neurologist, so I'm not in neuropathic pain.
Q. What is neuropathic pain?
A. My understanding of neuropathic pain is pain secondary to a nerve-induced neuropathy. It can come from a variety of -- can come from diabetic neuropathies, injury neuropathy, chemotherapy neuropathy, viral neuropathy, postherpetic neuropathies. Oftentimes intermixed with neuralgic pain.
Q. How many drugs in the United States are approved for the treatment of neuropathic pain?
A. I don't know. I don't know.
Q. Are there any?
A. I don't know.
Q. Are there any drugs approved in the

United States for diabetic neuropathy, for the treatment of diabetic neuropathy?
A. I don't know.
Q. Are there any drugs approved in the United States for the treatment of postherpetic neuralgia?
A. Neurontin is the only one that I know of.
Q. Okay. Are you an expert in the field of biostatistics?
A. We use biostatistics, of course, in -- in all of our assignments, but we hire a biostatistician to design the statistical components of our studies and to represent us, come with us to FDA for biostatistical issues.
Q. My question is as to you, Dr. Blume. Are you -- do you hold yourself out as a biostatistician?
A. Well, I thought I answered it. No, by training, I'm not a biostatistician. We do biostatistical work, but we ally ourselves with a biostatistician for that.
Q. So "we," being the PDG --
A. Yes.
Q. -- hires biostatisticians to help in the biostatistical analyses that you do for your clients, correct?

A. In the -- I mean, we don't hire biostatistician to interpret literature article, but we do hire a biostatistician to help us design the power of a clinical study or to help us evaluate animal data with regard to statistical issues, yes.
Q. And how about human data, do you -- do you personally run the biostatistical analyses of human data or do others do that in your practice?
A. Well, I thought I said clinical studies before I said animal. No, we use an outside biostatistician for clinical issues.
Q. In your report that was provided in this case, which is contained within Exhibit 5, were there any biostatistical analyses conducted to -- with regard to the relationship between Neurontin and suicidal behavior?
A. No, I did not. We do not do any statist- -- no. We do not do statistics on the pharmacovigilance data, no.
There were statistics done in your client's research reports in the studies that reported psychobiological events or suicide-related events, but we did not run any additional statistics on pharm -- pharmacovigilance work, no.
Q. Did you run any biostatistics on randomized

clinical trials; any analyses on that data?
A. No, but we report -- we reported the differences. We reported the -- the data that your client reported for those trials.
Q. But you, Dr. Blume, and Dr. -- or the PDG Group did not do biostatistical analyses of the clinical trial data as referenced in your report of --
A. Oh, no, I assumed the -- no, I just accepted the Pfizer numbers.
Q. Fine.
And do you know if Mr. Altman did any biostatistical analyses in connection with addressing the question of Neurontin and its association with suicide or suicidal behavior?
MR. FROMSON: Just note my objection as to form.
THE WITNESS: Well, yeah, I'm not aware of it.
BY MR. BARNES:
Q. Okay. Going on to neurobiology, do you hold yourself out as a neurobiologist?
A. No, I'm a pharmacologist. My -- my -- my specialty was -- our department in training was -- was neurobiology and endocrine biology. No, I don't hold myself out to be a neurobiologist.
I have several patents in neurobiology and

much of my work has been done with neurobiological end points, especially with the selegiline and desmethylselegiline. But notwithstanding those patents and that background, I would not consider myself a basic neuropharmacologist.
Q. Okay. And as to treatment of depression -- I know we've talked about -- about psychiatry. Do you hold yourself as an expert in the treatment of depression?
A. Well, not to be repetitive, but I'm not a physician, not a prescriber, not a psychiatrist, so, no, I don't hold myself out to be a depression expert. I mean, I've worked on NDAs with depression and -- and -- and --
Q. But you're not -- you don't treat it nor do you diagnose it, correct?
A. No, I'm not a physician.
Q. Okay. Now, when is the last time you published article in the peer-reviewed medical literature?
A. Not since I left -- not since Mylan, not since we finished the Mylan work.
Q. Can you tell me the date of your last peer-reviewed publication?
A. Literature publication, not the patent

literature?
Q. Peer-reviewed medical.
A. I think it was 10, 15 years ago. I don't have my CV in here.
Q. Let me find your CV. The CV you gave us had -- your report had more than that.
Now, let me hand you the same one. I'm going to hand you this. We won't mark it because I believe it's already in Exhibit 5, but that may help you answer the question.
A. 1990.
Q. So just so I understand, the last article published in the peer-reviewed medical literature by Cheryl Blume was in April of 1990; is that correct?
A. Yes.
Q. And you are listed as the fifth author on a medical article entitled "Absorption and Disposition of Low-Dose Combination Formulation of Hydrochlorothiazide and Triamterene;" is that correct?
A. No, it's Triamterene.
Q. Triamterene. Thank you.
That was published in "Biopharmacology Drug Dispositions"?
A. "Biopharmaceutics and Drug Disposition."
Q. Okay. Why haven't you published since 1990?

A. Working in industry, it's not very easy to publish, especially working in a small company. And just -- just haven't.
Q. Okay. Did any of your -- your published articles deal with postmarket surveillance techniques?
A. I doubt it. Well, there might be postmarketing information comparing the two products, but I doubt if there were surveillance techniques in those articles.
Q. The answer to my question is no --
A. I doubt it.
Q. You doubt it.
The best you can tell, you've never published on postmarket surveillance techniques, correct?
A. I -- I do -- I do not think so.
Q. Okay. Now, do any of these articles deal with the treatment of -- or diagnosis of epilepsy, that you've published?
A. No.
Q. Do any of them deal with the treatment and diagnosis of depression?
A. I think it's woven in our patents, depression, but it's not --
Q. Peer --
A. -- in publications.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: NEURONTIN MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

MDL DOCKET NO: 1629

Master File No. 04-10981

THIS DOCUMENT RELATES TO:

ALL PRODUCTS LIABILITY ACTIONS

VIDEOTAPED DEPOSITION OF:	CHERYL D. BLUME, Ph.D.
DATE:	November 13, 2007
TIME:	9:06 a.m. to 6:08 p.m.
PLACE:	13902 North Dale Mabry Highway Suite 122 Tampa, Florida
PURSUANT TO:	Notice by counsel for Defendants for purposes of discovery, use at trial or such other purposes as are permitted under the Federal Rules of Civil Procedure
BEFORE:	VALERIE A. HANCE, RPR Notary Public, State of Florida at Large
	Volume 2 Pages 371 to 722

similarity to gabapentin.
Q. That isn't my question. Listen to my question and you can answer this question, I would appreciate it.
My question is, do you have any factual basis to state that FDA would have approved the language concerning reduction of monoamine neurotransmitters after 2002 had Pfizer submitted it?
A. I have no information either way because I could find no records where they attempted to submit it again and have their labeling match pregabalin.
Q. So even if they -- but my question is, even had they submitted it, you have no basis to say that FDA would have acted favorably upon the submission, do you?
MR. FROMSON: Objection as to form.
THE WITNESS: Nor any reason to say they wouldn't have, especially since they've already approved that for pregabalin with the same mechanism.
BY MR. BARNES:
Q. Either way?
A. No, I have no information either way that they would have done that.
Q. Okay. Thank you.
Do you agree with Dr. McCormick's statement in her affidavit that the information regarding reduction

of monoamine neurotransmitters was not clinically important --
MR. FROMSON: Object --
BY MR. BARNES:
Q. -- so as to be included in -- in the language of the labeling?
MR. FROMSON: Objection.
THE WITNESS: I don't know where that comes from. It's not in the FDA record why it was struck. And other NDA's in other labeling clearly discuss the importance of neurotransmitters and perturbations in those transmitters, so I don't know what -- to what she's referring there.
BY MR. BARNES:
Q. Other than her -- her statement that it wasn't -- she's making the statement that in her view that deletion of the language regarding monoamines and GABA is supported by the conclusion that this information had little importance to a clinician for prescribing decisions. Do you see that?
MR. FROMSON: Objection.
THE WITNESS: Upon what she is relying, I do not know.
BY MR. BARNES:
Q. You're not a clinician or a prescribing

physician, correct?
A. Yeah, I think we discovered that.
Q. Yeah.
A. But I have no idea upon why -- upon what she's basing that nor how you can correlate that sentence with all of the other labelings that do exactly the opposite.
Q. And do you agree that -- do you have any reason to disagree with her statement there based upon your review of the Neurontin record?
A. Well --
MR. FROMSON: Objection.
THE WITNESS: -- I would say that it's -- her statement is somewhat incongruous with the labeling for other projects -- products that have the same actions and have amplified the labeling in the last couple years.
BY MR. BARNES:
Q. Let's go to another subject.
We've spoken about the biological plausibility, correct, in context of your opinions regarding Neurontin causing suicide, correct?
A. Yes.
Q. Are you aware of the average -- we're talking about the mechanism of action. We just spoke about GABA.

Are you an expert in the effect of GABA on the normal human brain?
A. No. I think I told you yesterday that I don't consider my neuropharmacologist and I know that there are other experts in this case that have been specifically asked to do that. I have read their reports. I would certainly defer to them in this, but I have a basic understanding of the role of neurotransmitters on various disease states and on behaviors and correction of disturbances and amelioration of certain disease states.
Q. Well, are -- do you -- are you going to express opinions concerning the mechanisms of action as to how Neurontin causes suicide from a pharmacol- -- pharmacology or toxicology point of view; the actual step by-step mechanism by which it occurs?
MR. FROMSON: Objection, form.
THE WITNESS: Okay. Is the question: Am I going to offer a pharmacologic opinion on the step -- the pharmacologic mechanism of action opinion on the step-by-step mechanism by which Neurontin pharmacologically step-by-step leads to suicide?
BY MR. BARNES:
Q. Yeah.

A. I don't think that's the definition of biologic plausibility, but I don't think I'll be offering that specific opinion because there are other – there are people who are going to be doing that.

Q. Okay. So define biological plausibility for me, as you use it in your testimony.

A. Biologic plausibility are those situations for which there are experimental, research, or other data which establish a relationship between an action and a either mediated event or a endpoint.

So there is a biologic plausibility for penicillin to cure certain infections because we understand that penicillin will destroy certain bacterial cell walls.

Q. Has any article in the published medical or scientific literature stated that it is biologically plausible that Neurontin causes suicide or suicide attempt?

MR. FROMSON: Just note my objection to the extent it may have been asked and answered.

THE WITNESS: Well, I think I have answered that article about – articles relating to causing suicide, but I will share with you the information I provided relating to Neurontin's actions on

transmitters that have been established to address mood and its – the impact of those transmitters, the correction of those problems on the changes in mood.

BY MR. BARNES:

Q. So you've cited those in your report, correct?

A. There is quite a lengthy section on that.

Q. Okay. What are the average concentrations of GABA in the normal human brain?

A. If I've cited it, I don't recall right now. But we know from other data that the average concentration in a brain is not a reflection for neurotransmitter activity in – in targeted tissue.

Certainly, the work with serotonin is -- is quite exhaustive. But serotonin levels, either the drugs that perturbate or serotonin systemic levels, are no -- are no prediction for events in relating to mood disturbances.

Q. Move to strike as unresponsive. That's not what I asked you. I asked you if you knew the average concentrations of GABA in the normal human brain.

A. No. And my answer is I do not.

Q. Okay. And how about the average concentrations of dopamine in the normal human brain?

A. Actually, I think I did quote the GABA levels.

Q. What is your opinion?

A. I think I did quote the GABA 10 to a hundred microliters in here.

Q. What paragraph?

A. 299. I start quoting. I need to review these. I think I do quote levels.

Okay. "Pfizer defendants acknowledge that the effects" – this is quoting – "effects of gabapentin on neurotransmitter release occur at drug concentrations that are relevant for pharmacologic actions of gabapentin in the employed animal models, 10 micromolar or translating that to 1.5 micrograms per mL."

THE REPORTER: A little slower, please.

THE WITNESS: Okay. I'll read it to you again. This is a quote.

"Pfizer defendants acknowledge that the effects of gabapentin on neurotransmitter" -- all one word -- "release occur at drug concentrations that are relevant for pharmacologic actions of gabapentin in animal models." Then in parentheses, "Approximately ten micromolar or 1.5 micrograms per mL."

Q. My question was in relationship to GABA. That document does not pertain to GABA, does it?

A. Oh, I thought you said "gabapentin." Let me

keep work -- let me keep working through this.

Q. My question was as to GABA.

A. Okay. Well, then we'll keep going.

MR. GUNTER: I tell you what. He needs to change the tape, so while she's looking, let's take a break.

MR. FROMSON: We can change the tape.

MR. BARNES: Look at GABA and look at dopamine and Norepinephrine -- Norepinephrine and --

MR. FROMSON: What's -- what's the specific question, Rick?

MR. BARNES: I just wanted to know -- I mean, she's going to talk about this mechanism of action, so I want to know what she knows about these neurotransmitters in the brain.

Norepinephrine, dopamine, GABA as an enzyme, as well as serotonin.

MR. FROMSON: Well, I appreciate your candor. Let's go off.

MR. BARNES: Yeah.

THE VIDEOGRAPHER: Off the record 2:13 p.m.

(Recess taken.)

THE VIDEOGRAPHER: On record 2:27.

BY MR. BARNES:

Q. You mentioned penicillin as being

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE,
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, deceased,
Plaintiff,

vs.

Civil No. 3:05-0444
Judge Aleta A. Trauger

PFIZER, INC. et al,

Defendants.

_____/

DEPONENT: Dr. Cheryl Blume

DATE: May 7, 2010
PLACE: Pharmaceutical Development Group
13902 N. Dale Mabry Hwy
Suite 230
Tampa, FL 33618

TAKEN: Pursuant to Notice by Counsel for Defendants
TIME: Began: 10:03 a.m.
Ended: 1:50 p.m.

REPORTED BY: PHILIP RYAN, RPR
Notary Public
State of Florida at Large

Gabapentin can cause suicidal behavior?

A. Yes, I believe that. But whether specific causation is shown is not necessary for information, labeling, and regulatory purposes. Specific causation is neither required for efficacy nor safety communications.

Q. Going back to my question, then, do you -- do you agree with the author's statement which you quote in your direct statement, that there is no clear understanding of a mechanism of action that could lead to suicidal behavior in patients taking antiepileptic medication.

A. Yes, I agree with that statement from my perspective. Of course there's other people who are going to be directly speaking to mechanism of causation.

Q. Do you agree with the authors' statement that the existing theories are not consistent and often derived from small trials generally performed against placebo in populations mainly including epileptic patients.

A. Well, again, I would agree that you read it correctly, but they are referring to very specific articles for which I have not

properties but at the same time are noting that conflicting behavior is reported in both children and adults in the form of aggression and stimulated or hyperactivity behavior.

Q. You would -- you would you agree the aggression and hyperactivity that they quote does not include suicide or suicide attempts; correct?

A. Again, I don't have those articles in front of me. Certainly aggression can lead to self-injurious behavior. But without having reviewed those references, I'm not -- I'm not sure I can answer the question.

Q. Do you agree that children are, in terms of average effect, are different from adults -- adults who are in the general population?

A. With respect to antiepileptic therapies?

Q. With respect to adverse events.

A. I read that adverse events may have -- may present differently or in different magnitudes or frequency in adults and children.

Q. And would you agree that adults with learning disabilities and cognitive impairment